

VIA FEDERAL EXPRESSFood and Drug Administration  
555 Winderley Pl., Ste. 200  
Maitland, FL 32751WARNING LETTER

FLA-01-32

February 12, 2001

Carlos G. Berdeal, President  
Carlos Seafood, Incorporated  
4041 NW 28<sup>th</sup> Street  
Miami, Florida 33142

Dear Mr. Berdeal:

We inspected your seafood importing and processing plant, located at the above address, on January 18-19, 2001 and found that you have serious deviations from the seafood processing (HACCP) regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your whole cooked lobsters, fresh mackerel and imported frozen lobster tails to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and these regulations through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

The deviations are as follows:

Domestic

You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, in order to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for whole cooked lobsters to control the potential food safety hazard of pathogens (this deviation was previously brought to your attention in our letter of July 30, 1998) or a HACCP plan for fresh mackerel to control the potential food safety hazard of scombrototoxin (histamine) formation.

Import

You must fully implement the affirmative steps you selected to ensure that the fish and fishery products you import are processed in accordance with the seafood HACCP regulations, in order to comply with 21 CFR 123.12(a)(2)(ii)(D). However, your firm does not perform the affirmative step of maintaining on file written guarantees from your foreign

Carlos G. Berdeal  
Page 2  
February 12, 2001

processors in addition to copies of their HACCP plans. For example, no written guarantees were available for frozen lobster tails manufactured by C & J Seafood, Inc., St. Elizabeth, Jamaica.

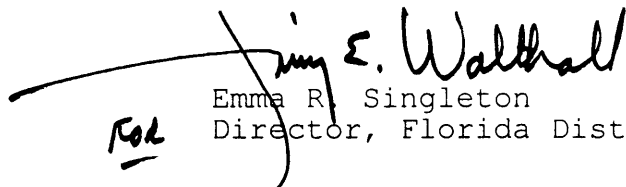
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of your HACCP plans, written guarantees or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your firm operates in compliance with the Act, the seafood processing (HACCP) regulations and the Good Manufacturing Practice (GMP) regulations for foods (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Jimmy E. Walthall, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Mr. Walthall at (407) 475-4731.

Sincerely,

  
Emma R. Singleton  
Director, Florida District

*For*